Rep. Henry A. Waxman
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I am pleased to join you today.

I want to thank Health Network Communications for holding this important conference. I always look forward to opportunities to applaud the generic drug industry for its tremendous work in bringing safe, effective, and low-cost drugs to American consumers, and to the world over. In the U.S. alone, generic medicines saved consumers and the nation's healthcare system over $1 trillion dollars over the past decade.

As we move into this new era of medicine marked by the ever-increasing presence of cutting-edge biologics, your efforts will continue to play a critical role in keeping our healthcare bill down.

This meeting is coming at the end of an exciting year for the U.S. generic drug industry. With the passage of the FDA Safety and Innovation Act, or "FDASIA" [pronounced Fe DAH Sya], we will start to see some important and concrete improvements in FDA's regulation of generic drugs and biosimilars. For the first time, FDA's generic drug program will finally benefit from an influx of resources through user fees. We also will see FDA's biosimilar review program truly get off the ground. These are tremendous achievements and I commend all of you for your efforts in working for these reforms.

When Congress considered this legislation earlier this year, one of my top priorities was to ensure that these and other important generic drug provisions in FDASIA were included in the final bill. That's because I know that in this time of economic crises and soaring health care costs, the availability of high quality generic drugs is more important than ever.

We need to find responsible ways to hold down health care costs without compromising the quality of care. Promoting good generic medicines policies is critical to this goal.

Generic Drug User Fees

Let me first talk about some of the key provisions in FDASIA.

As you are well aware, since the passage of the legislation commonly referred to as the 1984 Hatch-Waxman Act, the generic drug industry in the United States has grown by leaps and bounds. Today, generics comprise over 75% of the marketplace.

Despite this success, FDA's appropriations have not kept pace. This has resulted in a large backlog of applications and an unreasonably long wait for the review of ANDAs (Abbreviated New Drug Applications).

So the inclusion of the Generic Drug User Fee Act, or GDUFA [pronounced Ga-Doo-Fah], in FDASIA was incredibly important.

Over 20 years ago, the brand drug industry saw the advantage of providing FDA with user fees in return for more reviewers and shorter review times. Thanks to GDUFA, the generic industry will now see these same kinds of benefits. GDUFA will speed up review times and enable FDA to get through the backlog of applications currently in the queue.

The fees also will enable FDA to conduct more safety inspections of manufacturing facilities abroad. Under the agreement, for the first time, FDA will hold foreign and domestic facilities to the same risk based inspection standards.

After all this good work and successfully enacting this legislation, we have run into some road bumps. FDA's implementation of the program was put in jeopardy when Congress passed a continuing resolution to fund the government through March 2013 at essentially 2012 levels. GDUFA was written to enable FDA to set the deadlines for payment of the application and facility fees only after enactment of an appropriations act, not after a continuing resolution. No appropriations act, no payment deadlines.

Fortunately, I was able to work with Fred Upton, the chair of the Energy and Commerce Committee, and with Senators Harkin and Enzi, to craft an amendment to fix the problem. The President signed this into law just last month.

Unfortunately, we now have to contend with the possibility of sequester if we cannot reach a budget deal. Under sequestration, all federal agencies would get an 8% cut in nondefense discretionary federal spending.

FDA is in a particularly precarious situation here because the sequestration also threatens its user fee funds. If a certain threshold in appropriated funds is not met, FDA is prohibited from collecting user fee dollars.

This would obviously be problematic, to say the least, with respect to the newly established generic drug user fee program.

There are no clear answers on how sequestration will impact FDA. I'm hopeful that we will avoid it altogether. I will be watching this closely and doing all I can to prevent harmful effects to FDA's most critical programs.

Biosimilars

Another significant component of FDASIA is the Biosimilars User Fee Act, which will provide critical funds for FDA to get the biosimilars program up and running.

The Affordable Care Act, or ObamaCare as I now proudly like to call it, established a pathway by which generic biologics, or biosimilars, can come to market. I wanted biosimilar provisions that were more pro-consumer and less pro-brand-name drug company. But it is important to implement the provisions we have as effectively as possible.

Many generic drug companies are now actively engaged in developing new biosimilars. I have heard that FDA has already received at least a dozen I-N-Ds (Investigational New Drug applications) from companies preparing to begin clinical trials with biosimilars.

Meanwhile, FDA is working hard to set up the program and publish guidances and regulations. Some of the issues they are dealing with have important implications for the overall functioning of this program.

For instance, the issue of what to call the biosimiliar product presents some complicated questions. Obviously, with traditional drugs, the generic version and the brand version share the same nonproprietary name, also known as the international nonproprietary name, or INN [I-N-N]. But when it comes to biosimilars, FDA must decide whether to require the biosimilar version to come up with a unique nonproprietary name, different from that of the brand or reference product.

I am concerned that biosimilars will not achieve their full potential to lower the cost of new biotech drugs if they are forced to bear unique INNs. At the same time, FDA needs to be confident that a choice to follow the practice of Europe and the World Health Organization—which do not require unique INNs for biosimilars—will not lead to patient confusion or to medication errors. FDA must also be assured that using the same INN will not interfere with the ability of FDA and manufacturers to track adverse events.

This is a complicated and difficult issue. But I believe FDA will carefully consider it and resolve it in a way that both protects patients and ensures their access to these important medicines.

There is little dispute that biologics are part of the future of medicine. But these life-saving therapies will be worth little if no one can afford them. So we need to make sure that policies are in place that will permit biosimilars to fulfill their potential to bring competition to bear in this market. I will continue to fight to ensure that the biosimilars pathway is effective and results in meaningful cost-savings for Americans.

Drug Shortages

FDASIA also included some provisions intended to address the very difficult and urgent public health issue presented by drug shortages.

We have witnessed shortages affecting a broad spectrum of critically important drugs, including anti-cancer drugs and antibacterial drugs. Many of them are generic sterile injectables. FDA tells us that manufacturing problems are the most common causes of temporary supply interruptions. These manufacturing problems have presented significant health hazards, like contamination with glass shards, metal filings, or microbes.

FDASIA took one major step to address the shortages by requiring companies to notify FDA when there is an impending interruption in their supply of critical drugs. With such advance notice, FDA can work with companies to avoid or ameliorate the problem.

While this is certainly not a cure-all, I am hopeful that it will help to prevent some drug shortages and quickly resolve shortages that occur.

My staff and I have met with many of you and I know the generic drug industry is taking the shortage problem seriously. Several companies have indicated that they are investing in new or updated facilities to modernize the manufacturing of sterile injectable drugs. I hope that will alleviate shortages due to manufacturing problems or insufficient manufacturing capacity.

I know GPhA has also dedicated a great deal of effort on its Accelerated Recovery Initiative, which might serve to complement the notification provisions in FDASIA.

I applaud you for your efforts and I stand ready to continue to work with you to take steps to address this serious public health problem.

Drug Distribution Security

Let me turn now to a couple of provisions that did not make it into the final FDASIA legislation.

First, despite an enormous push by industry stakeholders and a tremendous amount of work by members and staff, we did not have enough time to reach consensus on how best to secure the drug distribution system.

Work to find a bipartisan, consensus solution has continued since the passage of FDASIA. In fact, we recently released a draft reflecting the breadth and depth of our discussions. That draft makes one thing abundantly clear: there continues to be strong disagreement around key areas of this legislation.

A large part of what is driving the push to enact federal legislation is the fact that California has already enacted a robust drug tracking and tracing system. Many of you in this room, along with other industry stakeholders, have concerns about that system—to put it lightly.

You should know that I am going to act to protect California's interests on this important issue.

I have been involved in many preemption battles over my career. What I have learned is that states act when the federal government fails to. If Congress were to enact a strong and effective federal program, states would welcome the federal leadership and the complications created by a patchwork of state laws would be avoided.

But such a federal program must accomplish certain goals. It must prevent or greatly minimize the possibility of stolen or counterfeit drugs entering the drug supply chain. A federal system must facilitate the swift identification and tracing back of any harmful product to its source.

And I think the only way to accomplish these goals is to put in place a unit-level tracking system that requires each link in the drug supply chain to verify the source of that drug at every step in the chain.

I want to stress that we need each part of the supply chain to participate. It is not worth trying to create a federal system if we are going to exempt major parts of the supply chain, like the dispensers. FDA, California, and all of the consumer and public health groups who have examined this issue agree with me on this.

There are cost and feasibility issues that need to be resolved.

An idealistic solution that is not practical benefits no one. But a system that does not require unit level tracking by all members of the supply chain is not one that should stop state action.

I will continue to work with all of you and with other stakeholders toward a consensus solution. But as I do so, these will be the fundamental goals I will have in mind.

Risk Evaluation and Mitigation Strategies (REMS)

There was one more key provision that failed to make it into the final FDASIA legislation.

When the Senate passed its version of FDASIA in June, it contained a provision that would have closed a loophole in FDA's drug safety authorities that has been exploited by the brand industry in their seemingly never-ending quest to thwart generic competition. I'm referring of course to "REMS" or "Risk Evaluation and Mitigation Strategies."

In 2007, on the heels of the Vioxx debacle, we gave FDA an array of new authorities to strengthen the agency's hand in assuring the post-market safety of drugs. One of those tools was the so-called "REMS," which allowed FDA to craft an appropriate post-market safety program to a particular drug.

While working on the 2007 legislation, we were concerned about the potential for brand companies to use the REMS as a means to prevent generic competition. We included some language to try to prevent this from occurring, but we failed to keep the more protective language that was included in the House-passed version of the 2007 legislation.

Sadly, the language we ended up with was apparently not strong enough and soon after enactment, we began to see abuse of the REMS, just as we feared.

Some brand companies patented their REMS and argued that FDA is prohibited from approving a generic drug that doesn't use the brand company's patented, and therefore unavailable, REMS plan.

Other brand companies used their REMS as an excuse not to provide their drug to generic companies for bioequivalence testing.

This year, the Senate passed a version of FDASIA that would have prevented brands from using the REMS as a basis for refusing to provide samples to generic firms for bioequivalence testing. CBO recognized the extent of this problem and told us that the REMS provision, along with other provisions in that bill, would have saved the federal government nearly $750 million over 10 years.

In the process of conferencing the House and Senate bills, unfortunately, we were not able to hold onto that provision.

This is a loophole we need to continue to work to close. There is no reason we should allow the brand industry continue to exploit a provision that Congress explicitly tried to safeguard from abuse—especially knowing the price tag for our inaction.

It is also important that we address this problem because REMS abuse may become a much bigger problem with biosimilars. Given the inherent risks associated with many biosimilars, it seems likely that most or all biosimilars will ultimately be covered by REMS. And the kind of comparability and bioequivalence testing required of biosimilars will likely require vastly more quantities of the reference biologic than are required for bioequivalence testing with generic drugs.

I will continue to look for opportunities to address this issue.

Conclusion

As all of you well know, the availability of high quality generic drugs is good for people all over the world. It is one of the most effective ways to hold down the costs of health care that we know. That is why I will continue to work to promote competition and innovation in our prescription drug industry and to increase the use of generic medicines worldwide.

I applaud all of you for the work you do every day to achieve this goal. And I thank you for this opportunity to speak with you.